Chronic Opioid Therapy
Safe Prescribing in Primary Care

Part 3

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Agenda

1. Review results of VISN 4 high dose opioid review and identify deficiencies in practice

2. Discuss system strategies that could be implemented to streamline and improve compliance with the required steps in chronic opioid prescribing

3. Through case scenarios, audience polling and questions, discuss specifics of practice:
   - Urine Drug Testing: tracking and responding to results
   - Methadone: EKG monitoring
   - Transferring opioid prescribing from non-va provider

National Strategy for Opioid Risk Mitigation

- **CDC, FDA, DEA**
  - Mandatory provider education
  - State prescription monitoring programs

- **VHA** – Opioid Safety Initiative
  - Standardizing COT prescribing in compliance with VA/DOD Guidelines
  - Focusing on high dose opioid prescribing

- **OIG**: In the process of reviewing all VHA facilities for compliance with VA/DOD Guidelines.

- **VISN 4**: High dose opioid review completed 3/29/13.

VISN 4 Summary Question		Total # Reviewed	% Appropriate	% Needs Improvement
1	**Pain Diagnosis** Pain diagnosis documented in the problem list/note	522	91%	9%
2	**Non-opioid treatment trials** Evidence of adequate trials of nonopioid modalities or documentation of adverse effects or contraindications for non-opioid modalities	497	72%	28%
2 a	Non-opioid modalities continue to be utilized appropriately	473	67%	33%
3	**Opioid Treatment Agreement in place**	475	**68%**	**32%**
4	**Urine Drug Screen** done at least twice a year for stable patients	512	**43%**	**57%**
4 a	Abnormal results are addressed and treatment plan adjusted	239	**75%**	**25%**
5	No **Aberrant behaviors** For example: pattern of early refills pattern of lost, stolen or missing medications frequent ER visits for pain meds frequent No Shows	490	76%	24%
5 a	Aberrant behavior addressed by the provider and treatment plan adjusted	211	73%	27%

	Question	Total # Reviewed	% Appropriate	% Needs Improvement
6	**EKG monitoring for methadone** EKG at baseline, when dose is stabilized, then annually QTc parameters: safety zone: < 450ms; risk range : 450-500ms; contraindicated : >/= 500ms	189	49%	51%
7	**Follow-up for reassessment at a minimum of every 6 months** Pain condition addressed in documentation Chronic opioid management assessed e.g. pain reduction and/or improvement in function, progress toward goals, manageable side effects, no aberrant behaviors	508	76%	24%
8	**Opioid Dosing** Opioid dose has been stable	511	81%	19%
8 a	Rationale for dose escalations is documented	234	72%	28%
	Overall assessment of chronic opioid management	**504**	**50%**	**50%**

Practice Rules for Chronic Opioid Prescribing (refer to handout)

(Chronic Opioids → > 3 consecutive months)

DECISION PHASE

1. Assessment is documented and diagnosis is in Problem List
2. Complete the "Opioid Risk Evaluation Note"
3. Opioid Treatment Agreement is MANDATORY
4. Urine Drug Testing is MANDATORY
5. Request for transfer of opioid prescribing to PVAMC

DOSE ADJUSTMENT PHASE

6. Follow evidence based guidelines
   - Close contact via Provider telephone contact, Nurse Clinic, Pharmacy Pain Management Clinic
   - EDUCATION (at staff meetings, online, via PACT virtual collaborative)
   - For further discussion and consensus: establishing dose limits, blocking hydromorphone

STABLE PHASE

7. Standardized Opioid Renewal Process
8. Monitoring and Documentation of adherence with monthly renewals – Opioid Renewal Template
9. Urine Drug Screens:
   - Urine drug screens are mandatory and should be obtained randomly at a minimum of every 6 months
   - If there is any evidence of non-adherence, drug screens should be done more frequently
   - In patients with active malignant disease or terminal benign disease, urine drug screening may be omitted
10. Inappropriate urine drug screens, early refills and escalating doses must be recognized as potential sign of substance misuse, addiction, diversion. Providers are responsible for documenting the aberrant behavior and the counseling and instructions given to patient in response.

STABLE PHASE continued

11. All patients on chronic opioid therapy will be seen by their provider at a minimum of q 6 months if stable and more frequently if needed (Develop Clinical Reminder ??)
12. Opioid Treatment Agreement will be reviewed and documented every 2 years(Develop Clinical Reminder??)
13. EKG for methadone: at baseline, when dose is stabilized, then annually (Develop Clinical reminder that includes the QTC parameters)
14. Providers should advise patients to return any unused medications to the pharmacy and the amount returned should be documented in the medical record

Attachments to Practice Rules:

1. PROCESS FOR RESTRICTING ACCESS TO CHRONIC OPIOID THERAPY WHEN DISCONTINUED FOR MISUSE

2. PROCESS FOR PATIENT REQUEST TO TRANSFER OPIOID PRESCRIBING TO VA

3. PRESCRIPTION DRUG MONITORING DATA BASE CHECKS – facility policy needs to be developed

Case #1 Mr. Dreamworld

- 55 yo patient transferring care to the VA after losing his private insurance.
- PMH: DM with neuropathy, Htn, Lumbar DDD
- Medications: glyburide, lisinopril, gabapentin, morphine SA 30mg BID, percocet 1 po BID prn. Patient has enough medication to last a month.
- Brings all his records from Dr. Smith including a report of his EMG, MRI, DAUs and a note from a neurosurgical consultation.

Case #1 Mr. Reality

- 38 yo patient transferring care back to the VA because his family doctor (Smith) is closing his practice. Hasn't been seen in VA system in 5 years.
- PMH: Htn, chronic low back pain, PTSD, h/o ETOH abuse, obesity, can't work because of pain and applying for SSDI
- Medications: lisinopril, oxycodone IR 30mg 1 po q4 hours prn # 150 a month. Family doctor prescribed just enough to get him to this appointment and patient took last pill this morning.
- Allergies: gabapentin, ibuprofen, morphine
- Has no records and doesn't have Dr. Smith's phone #.

Guidelines for transferring prescription opioid responsibility.

- **Opioids should not be started until all of the necessary information to make a safe decision is obtained**.
- Opioids should be continued by previous provider until appropriate information and assessment is completed
- Patient **MUST** obtain records from previous opioid prescriber **with contact information.**
- Make contact with previous provider to verify:
  - Current dose
  - Reason for prescribing opioid
  - Reason why opioid therapy is being terminated
  - Are there any aberrant behaviors?

Guidelines for transferring prescription opioid responsibility.

- Access the Prescription Drug Monitoring Data Base in NJ, WV, Ohio (and coming soon to PA)
- Perform Opioid Risk Evaluation
- Baseline urine drug screen should be completed at the first contact.
- *If the VA provider disagrees with opioid plan for any reason, they are not obligated to follow it. *
- Pharmacy formulary restrictions will be followed.
- Withdrawal can be managed medically.

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- Brings all his records from Dr. Smith including a report of his EMG, MRI, DAUs and a note from a neurosurgical consultation.
- After opioid risk assessment and contact with Dr. Smith it is likely reasonable to sign an OAA and take responsibility for his pain medication on the first visit.

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Case #1 Mr. Reality

- This patient does not get a prescription on his first visit.
- It remains to be determined if opioids are even indicated.
  - Young age
  - Opioids not allowing him to be functional
  - Presence of pathology?
- DAU this visit. Spine X-rays? Query PDMP. He needs to provide records and contact information for Dr. Smith.
- Establish at this visit that even if all the requirements for opioid prescribing are met under no circumstances will he be prescribed high quantities of highly potent short acting opioids.
- Methadone? Comprehensive multimodal pain treatment.

Case # 2

- 64 yo male with PMH of HTN, Type 2 DM, PTSD, Chronic pain secondary to Spinal Stenosis with radiculopathy

Pain has been well controlled on the following:

Methadone 30 mg q 8 hours (for years)
Amitriptylline 75 mg at HS
Gabapentin 800mg TID
Tizanidine 4 mg BID prn

Other meds include:

Lisinopril 20 mg daily
Metformin 500mg BID
Citalopram 40 mg daily
Quetiapine 100mg BID

He is in your Urgent Slot today to address an EKG that was done for pre-op assessment for elective podiatric surgery. The QTc is 512.

This is the only EKG in the system.

Poll Question #1

Methadone and QT interval

- **Screening EKG**: at baseline, when dose is stabilized, then annually. Additional monitoring is recommended if the methadone dose is > 100mg/day or if unexplained syncope or seizures
- **Risk Stratification:**
  - > 450 ms but < 500 ms: discuss risks and benefits and monitor more frequently
  - If > 500ms consider discontinuing or dose reduction; eliminating contributing factors such as other drugs that prolong QT , avoiding hypokalemia
- **Be aware of Drug Interactions:** clinicians should be aware of other drugs that possess QT interval – prolonging properties or slow the elimination of methadone.

Ehret, GB et al Arch Intern Med.2006;166:1280-1287; Bednar MM et al Am J Cardiol. 2002;89:1316-1319.

Question

- Which medications in this patient's list would be concerning for causing prolonged QT interval in addition to methadone?

	YES	NO
Amitriptyline 75 mg at HS	✓	
Gabapentin 800mg TID		✓
Tizanidine 4 mg BID prn	✓	
Metformin 500mg BID		✓
Citalopram 40 mg daily	✓	
Quetiapine 100mg BID	✓	

- Excellent review article:

"Clinical relevance and management of drug-related QT interval prolongation"

Identifies medications and categorizes them as definite, probable, proposed "torsadogenic"

http://www.medscape.com/viewarticle/458868_print

DAU Scenarios

- A sampling of some cases I've had recently.

Case #3

- 50 year old patient prescribed vicoden 1 po BID prn, prescribed 60 per month.
- Amphetamines, Qual, Urine-Negative
- Barbiturates , Qual, Urine-Negative
- Cocaine, Qual, Urine-Negative
- Methadone, Qual, Urine-Negative
- Opiate, Qual, Urine-Negative
- THC, Qual, Urine-Negative
- Benzodiazepenes, Qual, Urine-Negative
- Oxycodone Screen, Qual, Urine-Negative
- Ethanol, Qual, Urine-Negative

Poll Question #2

Case #3

- 50 year old patient prescribed vicoden 1 po BID prn, prescribed 60 per month.
- Amphetamines, Qual, Urine-Negative
- Barbiturates , Qual, Urine-Negative
- Cocaine, Qual, Urine-Negative
- Methadone, Qual, Urine-Negative
- Opiate, Qual, Urine-Negative
- THC, Qual, Urine-Negative
- Benzodiazepines, Qual, Urine-Negative
- Oxycodone Screen, Qual, Urine-Negative
- Ethanol, Qual, Urine-Negative

Case #3

- 50 year old patient prescribed vicoden 1 po BID prn, prescribed 60 per month.
- PRN prescribing means that it shouldn't be there all the time.
- At this low a dose the hydrocodone level may have fallen below the level of detection

Case #4

- 50 year old patient prescribed Oxycodone SA 20mg QID.
- Amphetamines, Qual, Urine-Negative
- Barbiturates , Qual, Urine-Negative
- Cocaine, Qual, Urine-Negative
- Methadone, Qual, Urine-Negative
- Opiate, Qual, Urine-Positive
- THC, Qual, Urine-Negative
- Benzodiazepines, Qual, Urine-Negative
- Ethanol, Qual, Urine-Negative

Poll Question #3

Case #4

- 50 year old patient prescribed Oxycodone SA 20mg QID.
- Amphetamines, Qual, Urine-Negative
- Barbiturates , Qual, Urine-Negative
- Cocaine, Qual, Urine-Negative
- Methadone, Qual, Urine-Negative
- Opiate, Qual, Urine-Positive
- THC, Qual, Urine-Negative
- Benzodiazepines, Qual, Urine-Negative
- **Oxycodone Screen, Qual, Urine-Positive**
- Ethanol, Qual, Urine-Negative

Case #4

- 50 year old patient prescribed Oxycodone SA 20mg QID.

- Oxycodone usually does not cause the opiate screen to turn positive. But sometimes it will.

Case #5

- 50 year old patient prescribed methadone 20mg QID.
- Amphetamines, Qual, Urine-Negative
- Barbiturates , Qual, Urine-Negative
- Cocaine, Qual, Urine-Negative
- Methadone, Qual, Urine-Positive
- Opiate, Qual, Urine-Positive
- THC, Qual, Urine-Negative
- Benzodiazepines, Qual, Urine-Negative
- Oxycodone Screen, Qual, Urine-Negative
- Ethanol, Qual, Urine-Negative

Poll Question #4

Case #5

- 50 year old patient prescribed methadone 20mg QID.
- Amphetamines, Qual, Urine-Negative
- Barbiturates , Qual, Urine-Negative
- Cocaine, Qual, Urine-Negative
- **Methadone, Qual, Urine-Positive**
- Opiate, Qual, Urine-Positive
- THC, Qual, Urine-Negative
- Benzodiazepines, Qual, Urine-Negative
- Oxycodone Screen, Qual, Urine-Negative
- Ethanol, Qual, Urine-Negative

Case #5

- 50 year old patient prescribed methadone 20mg QID.
- Methadone will not cause the opiate screen to be positive

Case #6

- 50 year old stable patient on Morphine SA 30mg po TID.
- Amphetamines, Qual, Urine-Negative
- Barbiturates , Qual, Urine-Negative
- Cocaine, Qual, Urine-Negative
- Methadone, Qual, Urine-Negative
- Opiate, Qual, Urine-Positive
- THC, Qual, Urine-Positive
- Benzodiazepines, Qual, Urine-Negative
- Oxycodone Screen, Qual, Urine-Negative
- Ethanol, Qual, Urine-Negative

Poll Question #5

Case #6

- 50 year old stable patient on Morphine SA 30mg po TID for 5 years s/p 3 low back surgeries.
- He has been your patient for several years and never had an abnormal DAU
- He has a remote history of substance abuse.
- Claims that he was in a car with some friends that were smoking marijuana.

Poll Question #6

Case #7

- 50 year old stable patient on Morphine SA 30mg po TID.
- Amphetamines, Qual, Urine-Negative
- Barbiturates , Qual, Urine-Negative
- Cocaine, Qual, Urine-Positive
- Methadone, Qual, Urine-Negative
- Opiate, Qual, Urine-Positive
- THC, Qual, Urine-Positive
- Benzodiazepines, Qual, Urine-Negative
- Oxycodone Screen, Qual, Urine-Negative
- Ethanol, Qual, Urine-Negative

Case #7

- 50 year old stable patient on Morphine SA 30mg po TID for 5 years s/p 3 low back surgeries.
- He has been your patient for several years and you had previously counseled him for testing positive for THC.
- Claims that he was in a car with some friends that were smoking marijuana and it must have been laced with cocaine.

Poll Question #7

Case #8

- 65 year patient with severe DJD on Morphine SA 100mg po TID.
- Amphetamines, Qual, Urine-Negative
- Barbiturates , Qual, Urine-Negative
- Cocaine, Qual, Urine-Negative
- Methadone, Qual, Urine-Negative
- Opiate, Qual, Urine-Positive
- THC, Qual, Urine-Negative
- Benzodiazepines, Qual, Urine-Negative
- Oxycodone Screen, Qual, Urine-Positive
- Ethanol, Qual, Urine-Negative

Poll Question #8

Case #8

- 65 year patient with severe DJD on Morphine SA 100mg po TID.
- The patient denies taking any medications except the ones you are prescribing for him.

Poll Question #9

DAU Interpretation Pointers

- Amphetamines- The amphetamine assay is the most difficult one to interpret due to a wide variety of common medications that can produce false positive results.
  - Bupropion, phenothiazines, TCAs, pseudoephedrine, ephedrine, phenylephrine & OTC decongestants.
  - Ritalin (methylphenidate) is a stimulant, but not an amphetamine and will not cause positive urine drug screen for amphetamine.
  - GC/MS conformation should always be sought.
- THC-Very Specific test with few agents causing false positives.
  - Even extensive passive exposure in an enclosed space is unlikely to result in a positive screen.
  - Length of time the drug can be detected is dependent on the degree of use. 3 days to six weeks.

DAU Interpretation Pointers

- Cocaine-"Cross-reactivity between this screen and substances other than cocaine are nearly non-existent. Urine screens for cocaine are very accurate in detecting *recent* cocaine ingestion."
  - However, the test may be less reliable because the length of time cocaine can be detected in the urine is short. 2-4 days.

DAU Interpretation Pointers

- A positive for opiates on the DAU screen may or may not be sufficient. In the majority of cases a GC/MS confirmation will be necessary as well. Make sure you lab has a policy for keeping DAU samples for a predetermined length of time.
- Patients on opiates may have a negative urine immunoassay and a positive GC/MS confirmation at low doses.
- The patient may be positive for non-prescribed opioids and unless you do the confirmation you will miss it.
- High doses of oxycodone *may* cause the opiate screen to be positive.
- High doses of morphine or other opiates *may* cause the oxycodone screen to be falsely positive.
- Poppy-seeds: can cause false positives for opiates.

DAU Interpretation Pointers

- Fentanyl is not identified by either the DAU or the normal confirmation process.
  - A special assay is required
- Oxycodone is metabolized to oxymorphone. For a patient taking oxycodone both may be detected via confirmation.
  - If only oxymorphone is present it implies that the oxycodone was not taken recently. Oxymorphone can last 1-2 days after oxycodone.
- Hydrocodone is metabolized into hyrdomorphone.
- Hydromorphone is not metabolized into hydrocodone.
- Benzodiazepene metabolism is complicated.
  - I have to check every time.

Urine Screening: Should the sample be witnessed?

- Always check the temperature.
- If it looks like water and is room temperature then it *is* water.
  - Consider checking the creatinine level
- Patients on prescription medications already have a signature to their urine which is difficult to duplicate
  - i.e. to fake a urine requires the patient to locate urine with the correct combination of prescribed meds and no illegal drugs and the patient must deliver that urine at body temperature.
- Screens for patients on no medications but looking to hide illegal drugs. Providing a false sample is perhaps easier, but still requires a high degree of sophistication.
- Unexpectedly high urine levels of a medication are indicative of the attempt to submit a false, positive sample.
  - Are there metabolites?

References for Urine Drug Testing

Drug Testing in the Workplace: could a Positive Test for One of the Mandated Drugs Be for Reasons other Than illicit Use of the Drug? Mahmoud A Elsohly. Journal of Analytical Technology. Vol 19, October 1995. 450-458.

Urine Drug Screening: Practical Guide for Clinicians. Moeller et. al. Mayo Clinical Proceedings. Jan. 2008; 83(1):66-76

Feldman L, Williams KS, Coates J, Knox M: Awareness and Utilization of a Prescription Monitoring Program Among Physicians. Journal of Pain & Palliative Care Pharmacotherapy 2011; 1–5. Perrone et al: Prescribing practices, knowledge and use of prescription monitoring programs by a national samp of clinicians, 2012 Presented at the June 2012 meeting of the National Alliance of State PDMP by **Jeanmarie Perrone, MD, FACMT** Associate Professor of Emergency Medicine Director, Division of Toxicology Perelman School of Medicine at the University of Pennsylvania and **Lewis S. Nelson, MD, FACMT** Professor, Emergency Medicine Director, Fellowship in Medical Toxicology New York University School of Medicine

Questions
&
Final Poll